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| WELTER, RACHAEL E | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/517,157 | BREITENBACH, ARMIN | |
| | Examiner | Art Unit | |
| | RACHAEL E. WELTER | 1611 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *19 May 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *12-32* is/are pending in the application.

4a) Of the above claim(s) *20-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-19 and 29-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/19/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Claim Status*

Claims 12-32 are pending. Claims 12-19 and 29-32 are directed to the elected species. Claims 20-28 are withdrawn. Claims 1-11 are cancelled. Claim 32 is newly added.

### *Acknowledgements*

Receipt of the amendment, replacement sheet for Figure 1, and arguments/remarks filed on 5/19/10 is acknowledged.

### *Information Disclosure Statement*

The information disclosure statement (IDS) submitted on May 19, 2010 was in compliance with the provisions of 37 CFR 1.97 and 37 CFR 1.98. Accordingly, the information disclosure statement was considered by the examiner. A signed copy of form 1449 is enclosed herewith.

### *New Rejections Necessitated by Amendment*

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12, 14-19, and 29-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The amendment of independent claim 12 does not comply with the written description requirement and introduces new matter into the patent application. Newly amended claim 1 recites "free of solubilizer" instead of "free of solvent." Applicant provides evidence in the form of Rule 1.132 Declaration, wherein Keith Ormand declares that a more appropriate translation of "solvent" in the instant specification is "solubilizer."

However, applicant's Declaration is insufficient because it implies that the certified English translation of the specification was inadequate when the US National Stage was entered. Each US National Stage entry from a foreign language PCT application comes certified with an English translation that attests that the accompanying translation is a true and correct translation into English. Thus, it is not clear to the examiner why Mr. Ormand's opinion should be given more weight than the certified English translation that accompanied the US National Stage entry.

Additionally, it is noted that applicant did not correct the English translation of the instant specification. The examiner directs applicant's attention to MPEP 714 and 37 CFR 1.121, which specifies the correct manner to amend the specification. Since the

word "solvent" is present throughout the specification, it is not necessarily clear whether applicant intended to amend all recitations of "solvent" to "solubilizer."

Thus, in light of the Declaration being insufficient and applicant not amending the English translation of the specification, it is the examiner's position that instant claim 12 lacks support for "free of solubilizer" in the specification.

Claims 14-19 and 29-32 are rejected as being dependent on a rejected base claim.

It is noted that a substitute specification may be needed. A substitute specification must not contain new matter. The substitute specification must be submitted with markings showing all the changes relative to the immediate prior version of the specification of record. The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived. An accompanying clean version (without markings) and a statement that the substitute specification contains no new matter must also be supplied. Numbering the paragraphs of the specification of record is not considered a change that must be shown. It is also recommended that a substitute specification in proper idiomatic English and in compliance with 37 CFR 1.52(a) and (b) be filed.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**Claims 12-19 and 29-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Farinas et al (US Patent No. 5,906,830) in view of Lauterbach et al (EP 1256340). The rejection of newly added claim 32 is appended to this rejection.**

Farinas et al teach methods for manufacturing transdermal drug delivery systems containing supersaturated drug reservoirs (abstract). According to Farinas et al, a backing layer serves as the upper surface of the device and is substantially impermeable to the drug (column 4, lines 6-9). In addition, Farinas et al teach a polymer-drug admixture that results in a system with two liquid phases, one that contains polymer and one that contains drug (column 6, line s 36-41). Drugs which may be incorporated into the transdermal systems include dopaminergic agonists and

antagonists in amounts of preferably 0.1-20 wt.% (column 7, line 45; column 8, lines 45-50). Farinas et al teach that the drug phase when quenched rapidly becomes an amorphous, glass phase at ambient conditions (column 6, lines 42-44). As evidenced, by Figure 1 of Farinas et al, the drug can be supersaturated in the form of particles in the reservoir layer. Furthermore, Farinas et al teach that if a solvent is used, it is removed during or before heat treatment (column 8, lines 7-9). Farinas et al do not teach the addition of any crystallization inhibitors or dispersants, including polyvinylpyrrolidone, and list that they are optional (column 8, lines 14-21). Finally, Farinas et al teach that the drug formulation may also include standard carriers or vehicles useful for facilitating drug delivery, like antioxidants (column 8, lines 14-16).

Farinas et al do not explicitly teach a transdermal drug delivery system comprising a rotigotine base or a matrix polymer that is amine-resistant silicone or a mixture of amine-resistant silicones.

Lauterbach et al teach a silicone-based transdermal therapeutic system that contains 0.1-3.15 mg/cm$^2$ of rotigotine as an active ingredient (abstract). According to Lauterbach et al, the silicone-based system must contain at least one amine resistant silicone compound as the main component (paragraph 0018). Lauterbach et al teach that usually the silicone compound will be a pressure sensitive adhesive and will form a matrix in which the other components of the system are embedded (paragraph 0017). Furthermore, Lauterbach et al teach the amounts of composition components in a table found in paragraph 0039. Rotigotine base is 9 wt.% and the amine resistant silicone compound is 89 wt.%. Moreover, Lauterbach et al teach the addition of antioxidants

such as ascorbyl palmitate, DL-alpha tocopherol, and sodium metabisulfate (table in paragraph 039). These antioxidants are present at 0.02 wt.%, 0.05 wt.%, and 0.0006 wt.% respectively.

Therefore, it would have been obvious to an artisan of ordinary skill at the time the invention was made to incorporate the active agent, rotigotine base, in combination with amine-resistant silicone into the transdermal patch of Farinas et al. One would have been motivated to do so since Farinas et al teach that dopaminergic agonists and antagonists can be used in its transdermal delivery systems and Lauterbach et al teach that the dopaminergic agonist, rotigotine base, is effectively used in transdermal systems. Furthermore, it is within the skill of an artisan to select rotigotine base as an active agent depending on the necessary treatment. Thus, an artisan would incorporate rotigotine base if one needed to treat patients with Parkinson Disease, as suggested in Lauterbach. Moreover, it would have been obvious to an artisan of ordinary skill at the time the invention was made to incorporate amine-resistant silicones in combination with rotigotine base in the transdermal delivery systems of Farinas. One would have been motivated to do so since the matrix polymer has good compatibility with rotigotine base and does not react with the amino group contained in rotigotine, as taught in Lauterbach (paragraph 0017).

Regarding the limitation, "...wherein the rotigotine base is in the form of amorphous particles with a maximum mean diameter of 30 um in the reservoir layer...", it is noted that Farinas et al do not teach a particle size of amorphous drug in the reservoir layer. However, when comparing the method of preparing the matrix in the

instant specification with Farinas et al, it is noted that Farinas et al and the instant invention have the same method of making the transdermal patch. The instant invention does not use any solvents, crystallization inhibitors, or dispersants because crystalline rotigotine is converted into the amorphous form by heating the matrix to a temperature above the melting point of rotigotine. Like the instant invention, Farinas et al teach heating an admixture of polymer and rotigotine to a temperature that is higher than the actual melting temperature of the pure drug contained in the formulation to provide a system containing two liquid phases, one liquid phase comprising polymer and one liquid phase comprising drug formulation (column 3, lines 56-67). Furthermore, Farinas et al teach that when the phase containing drug is quenched rapidly, it results in an amorphous, glassy phase at ambient conditions (column 6, lines 42-44). Farinas et al teach that this method is particularly useful for drug-polymer systems wherein the drug has relatively low solubility in the polymeric material, which is preferably silicone adhesives (column 6, lines 51-60). As such, since Farinas et al appear to have the same method of making the transdermal patch as the instant invention, it is the position of the examiner that rotigotine base as amorphous particles with a maximum mean diameter of 30 um in the drug reservoir layer would be an obvious expected result of the transdermal delivery system of Farinas et al and Lauterbach as *In re Spada, 911F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).* However, because the examiner has no access to laboratory equipment, burden shifts to applicant to prove otherwise as in *In re Fitzgerald, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).*

Regarding claims 29-31 and the newly added limitation, "storage stable for at least 6 months," it is the position of the examiner that since Farinas et al and Lauterbach et al teach the same amount of rotigotine base and all the components of the instant claims, these claim limitations would be intrinsic properties of the matrix for transdermal administration. Burden shifts to applicant to prove otherwise.

Regarding the new limitation "free of solubilizer," it is noted that Farinas et al do not explicitly teach that the addition of solubilizers is necessary for its transdermal delivery system. Additionally, if applicant is equating all solvents specified in the specification with solubilizers, it noted that the specification mentions solvents including heptane, ethyl acetate, and toluene (pg. 14, lines 3-4). Farinas et al teach that if a solvent is used, which includes ethyl acetate and toluene, it is removed during or before heat treatment (column 8, lines 1-9). As such, Farinas et al teach final transdermal delivery systems also free of solvent, including those solvents mentioned in the instant specification.

***Response to Arguments***

Applicant's arguments filed 5/19/10 have been fully considered but they are not persuasive.

Applicant notes that Farinas mentions at least six broad drug categories and thus applicant argues that there are well over a finite number of drugs to choose from. Applicant further argues that there are approximately 169 compounds that act on dopamine receptors. As such, applicant argues that an artisan would have to go

through a multistep selection process that could only be made in hindsight with guidance from applicant's specification to arrive at the claimed invention. Applicant argues that at best, an artisan would have to make eight selections plus an infinite number of sub-selections reading Farinas in view of Lauterbach without any guidance. Applicant directs the examiner to a flow chart on pg. 9 of their arguments.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Furthermore, the examiner maintains the position that it would have been obvious to an artisan of ordinary skill at the time the invention was made to select from the finite possibilities of drugs mentioned in Farinas and arrive at the instantly claimed invention. Even if there are 169 dopamine receptors and six broad categories of drugs taught in Farinas, it is noted that the number of drugs to choose from is still a finite number. In KSR v. Telefex, 82 USPQ2d 1385, 1397 (U.S. 2007), the Supreme Court has held that when there is market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person has good reason to pursue known options within his or her technical grasp. Under these conditions, "obviousness to try"

such options is permissible. Therefore, one would have been motivated to try a dopaminergic agonist with the elimination of solvent, crystallization inhibitor and dispersant with a reasonable expectation of success since Farinas suggests it within a finite number of identified possibilities. Applicant is further reminded that obviousness does not require absolute predictability, however, at least some degree of predictability is required. Evidence showing there was no reasonable expectation of success may support a conclusion of nonobviousness. *In re Rinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976). As such, the examiner has no burden to predict absolute failure and success but just motivation to believe that there would be a reasonable expectation of success. In this case, the examiner has no reason to believe that an artisan of ordinary skill would not have predicted success by incorporating rotigotine base in the transdermal delivery device of Farinas. Since Farinas teaches the possibility of many drugs, one would expect with a reasonable expectation of success that many different drugs would work within its compositions. Moreover, one would have been motivated to try rotigotine base if one desired to treat patients with Parkinson Disease, as suggested in Lauterbach.

With regard to selecting an amount of rotigotine free base and the selection of matrix polymers, one would have been motivated to select rotigotine base in an amount of 9 wt.% since Lauterbach suggests that the amount of drug is appropriate for transdermal compositions. It is also noted that Farinas teach drug in an amount of 0.1-20 wt.%. Additionally, one would have been motivated to select a matrix polymer consisting of amine-resistant silicone because Lauterbach suggests such a matrix has

good compatibility with rotigotine base and does not react with the amino group contained in rotigotine.

Applicant further argues that there is no guidance in Farinas to select amorphous particles with a maximum mean diameter of 30 um. Applicant argues that particle size depends on the drug employed, the formulation employed and the manufacturing process. Applicant notes that Farinas does not recite rotigotine or rotigotine base and does not disclose, teach, or suggest a matrix free of a solubilizer, crystallization inhibitor and dispersant.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). It is noted that the rejection is based on Farinas and Lauterbach not Farinas alone and as such, it is the examiner's position that the combination of teachings would result in the instant particle sizes. Applicant has not disputed that Farinas teaches the same process of making as the instant invention. Applicant also has not objectively shown that the combination of Farinas and Lauterbach would not result in the amorphous particles. Thus, the examiner maintains the position that rotigotine base as amorphous particles with a maximum mean diameter of 30 um in the drug reservoir layer would be an obvious expected result of the transdermal delivery system of the prior art.

Applicant further argues that there is no guidance for selection of a matrix absent solubilizer, crystallization inhibitor, and dispersant. Applicant argues that Lauterbach and WO '852 provide motivation toward using solubility enhancers, such as PVP in the matrix.

The examiner disagrees with applicant that the optional inclusion of crystallization inhibitors in Farinas would not lead an artisan to eliminate crystallization inhibitors in its transdermal delivery system. According to MPEP 2144, omission of an element and its function is obvious if the function of the element is not desired. *Ex parte Wu, 10 USPQ 2031 (Bd. Pat. App. & Inter. 1989).* Thus, even though Farinas teaches an advantage of inclusion but not exclusion of crystallization inhibitors, Farinas still teaches that crystallization inhibitors may be incorporated in its transdermal delivery systems. Moreover, according to MPEP 2121, "[t]he prior art's mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such a disclosure does not criticize, discredit, or otherwise discourage the solution claimed...." *In re Fulton, 391 F.3d 1195, 1201, 73 USPQ2d 1141, 1146 (Fed. Cir. 2004).* As such, just because Farinas teaches that it may be preferable to include crystallization inhibiters in its transdermal delivery system does not mean that Farinas is teaching away from the exclusion of crystallization inhibitors. Also, Farinas was only combined with Lauterbach to teach the obvious addition of rotigotine and amine-resistant silicone in the polymer matrix of Farinas. It is noted that Lauterbach is a secondary reference. WO '852 is not used in the rejection above and as such, it is not clear why applicant is arguing this reference.

Applicant further submits that instant Figure 4 in the specification shows in vitro rotigotine flow rates that are achieved after applying on human skin a system according to applicant's invention after 5 months storage. The figure also compares the instant invention to a system described in WO '852, which incorporates PVP. Applicant notes that in Figure 4, after 5 months storage, the release behavior of the TTS according to the instant invention remained unchanged. As such, applicant maintains that it would not have been predicted by one of ordinary skill in the art that a storage stable matrix could be prepared containing rotigotine base above its limit of solubility in the matrix polymer without solubilizers, crystallization inhibitors, or dispersants.

In response to applicant's unexpected results in Figure 4, it is the examiner's position that since Farinas and Lauterbach suggest all the components of the instant, the storage stability of the instant composition would be an intrinsic property. Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. *In re Wiseman*, 596 F.2d 1019, 201 USPQ 658 (CCPA 1979).

Second, it is noted that applicant's alleged unexpected results are not commensurate in scope with the instant claims. According to MPEP 716.02, whether the unexpected results are the result of unexpectedly improved results or a property not taught by the prior art, the "objective evidence of nonobviousness must be commensurate in scope with the claims which the evidence is offered to support." Independent claims 12 and 13 generically claim any matrix polymer and optionally any antioxidants in any amount. Merely showing one composition of the instant invention does not meet the huge scope of independent claims 12 and 13. As such, in order to

commensurate the scope of the instant claims with applicant's alleged unexpected evidence; applicant needs to narrow the scope of the instant claims.

Third, applicant has failed to show statistical significance of the data presented in Figure 4 given the standard deviation of the cumulative release at each time hour. According to MPEP 716.02, evidence relied upon should establish that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992.* Taking standard deviation into account, it looks like there is little different between the instant composition and that of WO '852.

Lastly, applicant argues that "a flow rate of rotigotine through human skin that is therapeutically effective, upon application of the system at intervals of 1 to 7 days," is not an obvious expected property of the invention. Applicant argues that since their matrix is free of a solubilizer, crystallization inhibitors, and dispersant, such a matrix is not taught or suggested.

It is noted that the examiner has addressed applicant's arguments regarding the prior art's guidance to make a matrix free of solubilizer, crystallization inhibitors, and dispersant above and they are incorporated herein. As such, since applicant's arguments are unpersuasive and it is the examiner's position that the cited prior art suggests all the components of the instant claims, the flow rate would be an intrinsic property of the matrix for transdermal administration.

Thus, absent any persuasive unexpected results, it is the examiner's position that the obviousness rejection should be maintained for the reasons stated above.

***Conclusion***

Claims 12-19 and 29-32 are rejected. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RACHAEL E. WELTER whose telephone number is (571) 270-5237. The examiner can normally be reached 7:30-5:00 Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached at 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

REW

/David J Blanchard/
Primary Examiner, Art Unit 1643